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UNITED STATES DISTRICT COURT
FOR THE CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

NATIONAL ASSOCIATION OF CHAIN DRUG STORES, ET AL.

Plaintiffs,

v.

ARNOLD SCHWARZENEGGER, ET AL.

Defendants.

No. 2:09cv7097 CAS (MANx)

STATEMENT OF INTEREST OF THE UNITED STATES OF AMERICA

DATE: December 7, 2009

TIME: 10:00 A.M.

BEFORE: Judge Snyder

UNITED STATES DEPARTMENT OF JUSTICE
CIVIL DIVISION, FEDERAL PROGRAMS BRANCH
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STATEMENT OF INTEREST OF THE UNITED STATES

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CASES **PAGE(S)**

STATUTES AND REGULATIONS

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INTRODUCTION

Pursuant to 28 U.S.C. § 517,[1] the United States of America respectfully submits this statement regarding issues arising under Title XIX of the Social Security Act of 1935, 42 U.S.C. § 1395 et seq. ("Medicaid"), and its implementing regulations, 42 C.F.R. § 430 et seq.

Plaintiffs, national and state pharmacist associations, ask this Court to enjoin California from "implementing" an approximately four percent reduction in Medicaid payments for prescription drugs that results from a four percent decrease in the published average wholesale prices ("AWPs") of these drugs. California's Medicaid program, called Medi-Cal, operates pursuant to a State Plan approved by the Secretary of Health and Human Services (the "Secretary") through the Centers for Medicare and Medicaid Services ("CMS"). Medi-Cal (like the State Plans of most state Medicaid programs) uses AWPs as part of its formula for determining reimbursement for pharmaceutical products. Each of the thousands of drugs covered by Medi-Cal has an AWP, which is neither set nor changed by Medi-Cal. AWPs, like other drug prices, fluctuate constantly in response to many different forces.

The four percent reduction in AWPs at issue here results from the settlement of a class action lawsuit charging that a publisher of drug pricing information (First DataBank) and a drug wholesaler (McKesson) unlawfully agreed to inflate the AWPs of over 1400 drug products. See Nat'l Ass'n of Chain Drugstores v. New England Carpenters Health Benefits Fund, 582 F.3d 30 (1st Cir. 2009). Specifically, the lawsuit alleged that First DataBank and McKesson fraudulently

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[1] Under 28 U.S.C. § 517, the United States may appear in any court in the United States "to attend to the interests of the United States in a suit pending in a court of the United States, or in a court of a State, or to attend to any other interest of the United States."

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increased the "markup" used to derive AWPs for certain products from 1.2 times the Wholesaler Acquisition Cost ("WAC") to 1.25 times the WAC. Id. at 36-37. As part of the settlement, First DataBank agreed to "rollback" the mark-up, reducing the published AWPs on certain prescription drugs by approximately four percent. Id.[2] Because Medi-Cal calculates drug payments by reference to the AWPs reported by First DataBank, the reduced AWPs stemming from the settlement necessarily resulted in a reduction in the state's payments for the prescription drugs at issue.

Although plaintiffs' lawsuit raises a variety of issues, the United States submits this brief to address only plaintiffs' claim that the reduction in AWPs caused by the First DataBank settlement requires Medi-Cal to submit a state plan amendment for approval by the Secretary through the Centers for Medicare and Medicaid Services ("CMS"). For reasons explained below, that claim should be rejected.

A change in the AWPs of particular products – like the reduction in AWPs caused by the First DataBank settlement – does not constitute a change by California in its operation of its Medicaid program, and therefore does not require California to amend its state plan. Like most states, Medi-Cal calculates payment rates for prescription drugs by reference to a formula rather than a fixed amount. The use of a formula produces varying payments depending on changes in the underlying data. Here, the First DataBank settlement resulted in a change in the published AWP, but California's methods and standards for setting prescription drug payments remain the same. Nothing in the Medicaid statute, its implementing regulations, or Ninth Circuit caselaw requires a state to amend its

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[2] States frequently establish drug payment methodologies based on the lowest of several alternative calculations. If the AWP-based calculation exceeds the amount calculated under one of the alternatives, the alternative calculation is used.

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plan whenever drug prices change,[3] and it is not the Secretary's policy to require any such amendment. A contrary conclusion would turn the district court's findings on which the settlement is based on their head, and would also severely impair the administration of the Medicaid Program, as states would be required to seek (and CMS would be required to review and approve) a plan amendment whenever AWPs (or other drug pricing information used to set reimbursement) are changed by publishers or manufacturers.

BACKGROUND

I. The Medicaid Program

The Medicaid program, established under Title XIX of the Social Security Act of 1935, 42 U.S.C. § 1395 et seq., pays for covered medical care provided to eligible indigent persons. "The program authorizes federal financial assistance to States that choose to reimburse certain costs of medical treatment for needy persons." Pharmaceutical Research & Mfrs. of Am. v. Walsh, 538 U.S. 644, 650, 123 S. Ct. 1855, 1861, 155 L.Ed.2d 889 (2003). To receive federal funding, a state must develop a "plan for medical assistance" and submit it to the Secretary of Health and Human Services for approval through CMS. 42 U.S.C. § 1396a(a); Wilder v. Va. Hosp. Ass'n, 496 U.S. 498, 502, 110 S. Ct. 2510, 2513, 110 L.Ed.2d 455 (1990). The state plan must provide, among other things:

> [S]uch methods and procedures relating to the utilization of, and the payment for, care and services under the plan . . . as may be necessary to . . . assure that payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area.

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[3] The basis for the change in AWP, whether it be a drug manufacturer's change in how it calculates wholesale acquisition cost ("WAC"), the drug compendia's change in its method of calculating AWP, a change in the actual acquisition costs themselves, market oscillations, or the settlement of litigation, is irrelevant. Medi-Cal's payment methodology is indifferent to the cause for the change in AWP.

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Id. § 1396a(30)(A). If a state plan does not comply with the Medicaid Act, the Secretary is authorized to withhold federal financial assistance. Id. § 1396c.

States are responsible for the day-to-day administration of their Medicaid program subject to certain federal regulations. Ark. Dep't of Health & Human Serv. v. Ahlborn, 547 U.S. 268, 275, 126 S. Ct. 1752, 1758, 164 L.Ed.2d 459 (2006). The Medicaid statute's implementing regulations require a state plan to "provide that it will be amended whenever necessary to reflect (i) Changes in Federal law, regulations, policy interpretations, or court decisions; or (ii) Material changes in State law, organization, or policy, or in the State's operation of the Medicaid program." 42 C.F.R. § 430.12(c)(1) (2009). In addition, CMS must review all amendments so as to "determine whether the plan continues to meet the requirements for approval." Id. § 430.12(c)(2). No provision in the Medicaid Act or the regulations requires a new plan amendment when published price points fluctuate.

II. California's Medicaid Plan

California has a CMS-approved Medicaid plan that describes how its Medicaid program, called Medi-Cal, is operated. Medi-Cal reimburses pharmacies for the cost of drugs plus a fixed dispensing fee per prescription. Cal. Welf. & Inst. Code § 14105.45. To determine how much to reimburse providers for a given drug, Medi-Cal calculates the lowest of four amounts: (1) "the Average Wholesale Price (AWP) minus 17 percent," (2) "the Maximum Allowable Ingredient Cost (MAIC)," (3) "the federal upper limit of reimbursement for listed multiple source drugs," or (4) "the charges to the general public." Cal. Medicaid Plan, Attachment 4.19-b, Supp. 2(A). Like most state Medicaid programs, Medi-Cal obtains AWPs from First Data Bank. In addition to payment for the drug

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itself, California pays a dispensing fee which is currently $7.25 per prescription and $8.00 for drugs dispensed to residents of nursing facilities or intermediate care facilities. Cal. Medicaid Plan, Attachment 4.19-b, Supp. 2(B).

III. Factual Background

First DataBank is one of several compendia that compile and publish drug pricing information including WACs and AWPs. As noted above, many state Medicaid programs, as well as third-party payors, use First Data Bank's pricing information in calculating reimbursement for prescription drugs.[4] Historically, AWPs provided a common pricing point for third-party payors to process millions of drug transactions. In re Pharmaceutical Indus. Average Wholesale Price Litig., 491 F. Supp. 2d 20, 32 (D. Mass. 2007).

Unfortunately, AWPs are vulnerable to manipulation. Drug manufacturers and drug pricing compendia – not state Medicaid agencies – control the AWPs, either by reporting AWPs directly or by reporting WACs to which the manufacturer knows the compendia will apply a formulaic mark-up to generate AWPs. See Massachusetts v. Mylan Labs, 608 F. Supp. 2d 127,137 (D. Mass. 2008); In re Pharmaceutical Indus. Average Wholesale Price Litig., 491 F. Supp. 2d at 33. Drug manufacturers' practice of reporting inflated AWPs has generated extensive litigation, including lawsuits brought by the United States Department of Justice, more than twenty states, and various third-party payors. In this

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[4] AWPs were also used by the federal government for Medicare Part B reimbursement until the passage of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (December 8, 2003). See In re Pharmaceutical Indus. Average Wholesale Price Litig., 491 F. Supp. 2d at 32.

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litigation, courts have construed the term "Average Wholesale Price" according to its plain terms, holding that it is "the average price at which wholesalers sell drugs to their customers, including physicians and pharmacies." See, e.g., id.; In re Pharmaceutical Industry Average Wholesale Price Litigation, 582 F.3d 156, 169-72 (1st Cir. 2009).

Accordingly, courts have held that reporting inflated AWPs which do not reflect actual prices constitutes unfair and deceptive conduct. The district court in Massachusetts found that published "AWPs are fictitious and are rarely, if ever, prices paid by doctors . . . or by pharmacies." In re Pharm. Indus. Average Wholesale Price Litig., 491 F. Supp. 2d at 94. The "megaspreads" between stated AWP and actual acquisition cost, the court explained, far exceeded "well-established industry expectations," sometimes reaching "as high as 1,000%." Id. at 95. Moreover, the court found that defendants had acted deliberately in that case, with full knowledge that "neither the government nor the [third party payors] could do much to change the AWP reimbursement benchmark because they were locked into the nationwide reimbursement scheme established by statute or contract." Id. at 94-95. Criticizing the "perverse incentive" created by the payment system, which put "the proverbial pharmaceutical fox in charge of the reimbursement chicken coop," the court concluded that the "different pharmaceutical companies unfairly took advantage of the system by setting sky high [average wholesale] prices with no relation to the marketplace." Id. at 95. See also id. ("Unscrupulously taking advantage of the flawed AWP system for Medicare reimbursement by establishing secret mega-spreads far beyond the standard industry markup was unethical and oppressive").

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The First DataBank class action lawsuit is another example of the problems created by abuse of the AWP system. Claiming that AWP numbers reported by First DataBank were inflated, third-party payors filed a class action lawsuit in 2005. In approving the settlement of the litigation, the district court found that as a result of the collusion between First Data Bank and McKesson, pharmacies "were unjustly enriched when drug prices were fraudulently inflated during the scheme, yet they have not been asked to disgorge their profits." New England Carpenters Health Benefits Fund v. First DataBank, Inc., 602 F. Supp. 2d 277, 284 (D. Mass. 2009). The Court specifically found that "rolling back AWPs" was "in the public interest and to the benefit of the class." Id. at 283.

The pharmacist associations who now are the plaintiffs in this case appealed the First DataBank settlement unsuccessfully to the First Circuit, see Nat'l Assoc. of Chain Drug Stores v. New England Carpenters Health Benefits Fund, 582 F.3d 30 (1st Cir. 2009), and the reduced AWPs became effective on September 26, 2009. Three days later, plaintiffs brought this action against California and, on October 2, 2009, moved for a preliminary injunction to stop the payment reduction.[5] In essence, by seeking to retain the same profits the district court

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[5] Plaintiffs have filed similar suits seeking declaratory and injunctive relief in New York, Washington, and Minnesota. See Pharmacists Soc'y of State of N.Y. et. al. v. Paterson et. al., No. 1:09-cv-01100-LEK-GHL (N.D.N.Y.); Wash. State Pharmacy Assoc. v. Gregoire et. al., No. 2:09-cv-01377-RAJ (W.D. Wash.); Minn. Pharmacists Assoc. et. al. v. Pawlenty et. al., No. 0:09-cv-02723-DWF-RLE (D. Minn.). The United States intends to file a Statement of Interest in each of those cases as well.

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found to be unjust, plaintiffs are attempting to relitigate in this court issues they raised (and lost) before the First Circuit.[6]

ARGUMENT

I. California is not required to amend its state plan in response to the change in published average wholesale prices produced by the First DataBank settlement.

Plaintiffs assert that California was required to submit a state plan amendment to the Secretary for approval before "implementing" the four percent reduction in payments for prescription drugs automatically triggered by the four percent reduction in published AWPs resulting from the First Data Bank settlement. Pls. Motion Supp. Prelim. Injunc. at 12-13. In support of this argument, plaintiffs characterize the payment reduction as a "material change" in the state's Medicaid plan for which the Secretary's approval was required. Id. at 13. Plaintiffs' theory finds no support in the Medicaid statute, in its implementing regulations, in the caselaw, or in years of practice by the Secretary. What is more, acceptance of plaintiffs' position would impose impossible administrative burdens on states and the federal government in administering the Medicaid program.

1. Neither the Medicaid statute nor any implementing regulation requires a state to amend its Medicaid State Plan whenever drug pricing compendia change their estimates of AWPs, regardless of the basis for the changes. The Medicaid statute limits federal financial assistance to those states "which have submitted, and had approved by the Secretary, State plans for medical assistance." 42 U.S.C. § 1396-1. In compliance with the plain terms of the statute, California has

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[6] The United States recognizes that plaintiffs did not raise their claim regarding the need for a state plan amendment before the First Circuit.

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submitted, and had approved by the Secretary, a plan for medical assistance. Plaintiffs do not contend otherwise.

Instead, plaintiffs emphasize that federal regulations require a state plan to "provide that it will be amended whenever necessary to reflect (i) Changes in Federal law, regulations, policy interpretations, or court decisions; or (ii) Material changes in State law, organization, or policy, or in the State's operation of the Medicaid program." 42 C.F.R. § 430.12(c)(1). In addition, plaintiffs point out, CMS must review all plan amendments to "determine whether the plan continues to meet the requirements for approval." Id. § 430.12(c)(2). These provisions establish, in plaintiffs' view, that "CMS must approve all amendments to a State plan before a state may implement" what plaintiffs claim to be "'material changes' to its Medicaid program including those made to 'reflect . . . court decisions' such as the First DataBank settlement." Pls. Motion Supp. Prelim. Injunc. at 13. This is nonsense.

The United States has no quarrel with plaintiffs' assertion that all state plan amendments must be approved by CMS or that a state plan must provide that it will be amended whenever "necessary to reflect" significant changes. If California chose to modify its payment formula by increasing the discount applied to AWP, for example, it would be required to submit a plan amendment to CMS for approval before implementing the change. If "[c]hanges in federal law, regulations, policy interpretations, or court decisions" required a modification to California's payment methodology, a CMS-approved plan amendment would

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likewise be required. The United States does not understand California to assert otherwise.[7]

That, however, is nothing like what happened here. California had nothing to do with the First DataBank settlement, and has not changed its reimbursement methodology at all. Although plaintiffs, in similar cases filed in New York, Minnesota, and Washington allege that the rate reduction was a "decision" by the state to "adopt a new definition of average wholesale price.," see Pl.'s Mem. Supp. Prelim. Injunc. at 8 (N.D.N.Y.); Pl.'s Mem. Supp. Prelim. Injunc. at 1 (D. Minn.), California did not make any "decision" to "adopt a new definition" of anything. That certain published AWPs changed as a result of litigation to which California was not a party is plainly not California's doing. Indeed, the state has retained the methodology for calculating prescription drug payments contained in its CMS-approved state plan. Thus, no amendment was "necessary to reflect" the four percent reduction in AWPs following the First DataBank settlement, 42 C.F.R. § 430.12(c), meaning that California was not required to "implement" anything nor amend its state plan. So long as CMS approves a state plan that ties payment rates to AWPs, as it did with Medi-Cal, no plan amendment is required when AWPs fluctuate up or down.

2. Not surprisingly, plaintiffs cannot identify any case that supports their position. The two cases plaintiffs rely upon are inapplicable here because they

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[7] Indeed, when California has changed its methods or standards of setting payments in the past, it has sought and obtained CMS's approval. On September 1, 2004, for example, California changed its payment formula from AWP minus ten percent to AWP minus seventeen percent. It also increased the dispensing fee from $4.05 to $7.25 per prescription. Gorospe Decl. ¶ 14. California amended its state plan, and obtained federal approval, before implementing these changes. Id.

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involve either state regulation that conflicted with the state plan or a state's implementation of a plan amendment without obtaining prior federal approval. Washington State Health Facilities Association v. State of Washington Department of Social and Health Services, 698 F.2d 964 (9th Cir. 1982), for example, involved an injunction barring enforcement of a "state regulation" that "deviate[d] from the official state plan by altering the method of reimbursing nursing care facilities that accept Medicaid patients." Id. at 965. Similarly, Exeter Memorial Hospital Association v. Belshe, 145 F.3d 1106 (9th Cir. 1998), dealt with California's "implementation of amendments to Medi-Cal . . . before the amendments were approved by the federal government." Id. at 1107. These cases are irrelevant here, where California did not implement anything nor change its Medicaid program. Indeed, the relief plaintiffs seek in this case would force California to *violate* its state plan, and federal law requiring the state to submit all plan amendments to CMS for approval, by requiring the state to deviate from its CMS-approved AWP minus 17% formula.

3. That plaintiffs' position has no support in the Medicaid statute, its implementing regulations, or the caselaw is reason enough to reject it. But there remains another reason. Taken to its logical conclusion, plaintiffs' argument is that a plan amendment, requiring federal approval, is necessary every time a state modifies its payments as a result of fluctuations in AWPs. This novel theory would impose impossible burdens on state Medicaid programs and the federal government. Each of the thousands of drugs covered by Medi-Cal has its own unique AWP; each such AWP frequently rises and falls in response to many different pressures including market forces and, as here, the settlement of litigation involving charges that AWPs were fraudulently inflated. Plaintiffs' position – that

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a plan amendment is necessary each time prices change – would require almost constant amendment of state plans and likely result in payment delays, reducing access to prescription drugs for the nation's most vulnerable citizens. Id.

The result should be no different merely because the AWP fluctuation in this case stems from litigation. As is apparent from the extensive multi-district AWP litigation over the past decade, drug pricing compendia and drug manufacturers have grossly overstated many AWPs, resulting in billions of dollars in losses to third-party payors and states. Any adjustment in stated acquisition costs or wholesale prices that would make the published prices more accurate is long overdue.[8]

CONCLUSION

For the foregoing reasons, the United States respectfully urges this Court to conclude, in support of longstanding and consistent federal policies, that California was not required to submit a state plan amendment before implementing the four percent reduction in payments for prescription drugs.

Dated: December 4, 2009

Respectfully submitted,

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/s/ Ethan Davis
ETHAN P. DAVIS
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U.S. Department of Justice

[8] The United States is considering whether to file a Statement of Interest on other issues presented in this case.

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PROOF OF SERVICE BY MAILING

I am over the age of 18 and not a party to the within action. I am employed by the Office of United States Attorney, Central District of California. My business address is 300 North Los Angeles Street, Suite 7516, Los Angeles, California 90012.

On December 4, 2009, I served STATEMENT OF INTEREST OF THE UNITED STATES OF AMERICA on each person or entity named below by enclosing a copy in an envelope addressed as shown below and placing the envelope for collection and mailing on the date and at the place shown below following our ordinary office practices. I am readily familiar with the practice of this office for collection and processing correspondence for mailing. On the same day that correspondence is placed for collection and mailing, it is deposited in the ordinary course of business with the United States Postal Service in a sealed envelope with postage fully prepaid.

Date of mailing: December 4, 2009. Place of mailing: LOS ANGELES, CALIFORNIA. **Person(s) and/or Entity(ies) to Whom mailed:**

Yvette D. Roland
Audra L. Thompson
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I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

I declare that I am employed in the office of a member of the bar of this court at whose direction the service was made.

Executed on: December 4, 2009 at Los Angeles, California.

Olivia Murillo